APR 3 0 2004

3. 510(k) Summary of Safety and Effectiveness

a. General Information

Modified Device Information

Category:	Comments:
Sponsor:	Boston Scientific Corporation 2710 Orchard Parkway San Jose, Ca 95134
Correspondent:	Ronald C. Allen, Ph. D. Manager, Regulatory Affairs Boston Scientific Corporation 2710 Orchard Parkway San Jose, Ca 95134
Contact Information:	E-mail: allenr@bsci.com Phone: (408) 895-3670 Fax: (408) 895-2202
Device Common Name:	Pericardiocentesis Kit
Device Proprietary Name:	PeriVac Kit
Device Classification:	Class II

Predicate Device Information

Predicate Device:	PeriVac Kit
Predicate Device Manufacturer:	Boston Scientific Corporation
Predicate Device Common Name	Pericardiocentesis Kit
Predicate Device Classification:	Class II
Predicate Device Classification Number:	21 CFR §870.1330

b. Date Summary Prepared

March 28, 2004

c. Description of Device

The PeriVac Kit is designed to provide all of the necessary components for site preparation, local anesthesia, puncture, aspiration and/or drainage, collection, and dressing for the completion of pericardial fluid aspiration. The kit is comprised of finished components and packaged to provide convenience for the user.

The PeriVac Kit is comprised of 21 components pre-assembled and packaged to eliminate delays when initiating emergency pericardial aspiration of fluid. For customer convenience, the PeriVac Kit will be made available in four packaging configurations with the only difference between the kits being the catheter types and the inclusion or exclusion of Lidocaine and Providone-Iodine solution. This submission addresses two components of the PeriVac Kit.

d. Intended Use

The intended use for the PeriVac Kit is as follows:

The PeriVac Kit is intended for use in pericardial aspiration and drainage in the presence of pericardial effusion ~~and~~ OR tamponade.

e. Comparison to Predicate Device

See Table I- Comparison of Device Characteristics to Predicate on the following page.

Table 1 - Comparison of Device Characteristics to Predicate

	CLEARED KIT	PREDICATE KIT	
FEATURE	**PeriVac Kit**	**Mansfield Kit**	**Current Submission**
510(k) Reference Number	K032050	Pre-Amendment	
Product Code	DQX	-	DQX
Classification Section	21CFR 870.1330	21CFR 870.1330	21CFR 870.1330
Classification Name	Convenience Kit	Convenience Kit	Convenience Kit
Indications for Use	The Pericardiocentesis Kit is intended for use in pericardial aspiration and drainage in the presence of pericardial effusion or tamponade.	The Pericardiocentesis Kit is intended for use in pericardial aspiration and drainage in the presence of pericardial effusion or tamponade.	The Pericardiocentesis Kit is intended for use in pericardial aspiration and drainage in the presence of pericardial effusion or tamponade.
Anatomical Sites	Pericardium	Pericardium	Pericardium
Method of Use	The Pericardium is entered via a series of progressively larger positioning of needles, guidewire, dilator, and catheter positioning. Once confirmed in position, fluid contained in the pericardium is drained into a graduated bag. Upon completion the catheter is withdrawn and the entry site closed.	The Pericardium is entered via a series of progressively larger positioning of needles, guidewire, dilator, and catheter positioning. Once confirmed in position, fluid contained in the pericardium is drained into a graduated bag. Upon completion the catheter is withdrawn and the entry site closed.	Same
Power Source	None	None	None
Sterilization Method	ETO	ETO	ETO

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	CLEARED KIT	PREDICATE KIT	
FEATURE	PeriVac Kit	Mansfield Kit	Current Submission
Pyrogen Free	Non-pyrogenic	Non-pyrogenic	Non-pyrogenic
Expiration Date (years)	Two year	One year	Two year
Single Use Only	Yes	Yes	Yes
Packaging	Thermoform Tray, Wrapped in CSR Wrap, and sealed in Header Pouch	Thermoform Tray, Wrapped in CSR Wrap, and sealed in Header Pouch	Thermoform Tray, Wrapped in CSR Wrap, and sealed in Header Pouch
Packaging Contents	The 21 components provided in the PeriVac Kit are presented in Table 4.	The 17 components provided in the Mansfield kit are presented on the product label (Appendix D).	The 21 components provided in the PeriVac Kit are presented in Table 4.
Contraindications	There are no known contraindications for pericardial aspiration, although recurrent effusion or unresolved tamponade may warrant surgical intervention.	There are no known contraindications for pericardial aspiration, although recurrent effusion or unresolved tamponade may warrant surgical intervention.	There are no known contraindications for pericardial aspiration, although recurrent effusion or unresolved tamponade may warrant surgical intervention.

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Warnings and Precautions	• Inspect all devices and equipment prior to use. Ensure that sterile barrier has not been breached. • Careful attention to aseptic technique should be employed. • This kit should be used only by persons thoroughly trained in the techniques of pericardial centesis. • Take proper care to ensure that patient-contact electrical equipment is properly isolated and grounded. • STERILE. For one procedure only. Do not resterilize. • CT scan, fluoroscopic, or echocardiographic examinations are recommended to evaluate needle and catheter placement. • Pericardiocentesis should be carried out in the Special Procedures Laboratory or Cardiac Catherization Laboratory, utilizing equipment capable of cardiac monitoring. When performed at bedside, electrocardiographic monitoring should be employed continuously.	• Inspect all devices and equipment prior to use. Take proper care to ensure that all patient-contact electrical equipment is properly isolated and grounded. Do not wipe catheter with organic solvents (e.g. alcohol, ethers, esters, phenols, etc.). Careful attention to aseptic technique should be employed.	• Inspect all devices and equipment prior to use. Ensure that sterile barrier has not been breached. • Careful attention to aseptic technique should be employed. • This kit should be used only by persons thoroughly trained in the techniques of pericardial centesis. • Take proper care to ensure that patient-contact electrical equipment is properly isolated and grounded. • STERILE. For one procedure only. Do not resterilize. • CT scan, fluoroscopic, or echocardiographic examinations are recommended to evaluate needle and catheter placement. • Pericardiocentesis should be carried out in the Special Procedures Laboratory or Cardiac Catherization Laboratory, utilizing equipment capable of cardiac monitoring. When performed at bedside, electrocardiographic monitoring should be employed continuously. • Replace the straight catheter with pigtail catheter (sold separately) if drainage is required for up to 24 hours. Do not leave the pigtail catheter in longer than 24 hours. • Secure the pigtail catheter to the skin and apply a sterile dressing. • At the time of catheter

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f. Summary of the Non-clinical Data

Where appropriate, testing conformed to the requirements of 21 CFR Part 58 (Good Laboratory Practices (GLP)). Specifically, non-clinical tests conducted for the Device showed the device met its design-input criteria, and was safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 0 2004

Boston Scientific Corp.
c/o Dr. Ronald Allen
EP Technologies, Inc.
2710 Orchard Parkway
San Jose, CA 95134

Re: K040867
PeriVac Kit, models 4304, 4305, 4314, and 4315
Regulation Number: 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: March 28, 2004
Received: April 2, 2004

Dear Dr. Allen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

In addition, we have determined that your device kit contains 5 ml of 1% HCL Lidocaine which are subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers,

International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/dsma/dsmamain.html

Sincerely yours,

Donna R. Lechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification -Indication for Use Statement

Device Name: PeriVac Kit

Indication for Use:

The intended use for PeriVac Kit is as follows:

The PeriVac Kit is intended for use in pericardial aspiration and drainage in the presence of pericardial effusion or tamponade.

Prescription Use____X_____ **Over-the-Counter Use_____**
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IS NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K